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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/067,148	05/26/1993	LUC MONTAGNIER	3495.000404	5174

22852 7590 07/30/2002

FINNEGAN, HENDERSON, FARABOW, GARRETT &
DUNNER LLP
1300 I STREET, NW
WASHINGTON, DC 20005

EXAMINER

PARKIN, JEFFREY S

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 07/30/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/067,148

Applicant(s)

MONTAGNIER, L., ET AL.

Examiner

Jeffrey S. Parkin, Ph.D.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 03 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 April 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-31 and 37-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29-31 and 37-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

Response to Amendment

Status of the Claims

1. Acknowledgement is hereby made of receipt and entry of the communication filed 15 April, 2002. No amendments to the claims or specification accompanied the response. Claims 29-31 and 37-44 are pending in the instant application.

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35 U.S.C. § 112, First Paragraph

2. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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3. Claims 29-31 and 37-44 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *In re Rasmussen*, 650 F.2d 1212, 211 U.S.P.Q. 323 (C.C.P.A. 1981). *In re Wertheim*, 541 F.2d 257, 191 U.S.P.Q. 90 (C.C.P.A. 1976). Claims 29-31 are drawn toward immunological complexes comprising a purified HIV-1 antigen (e.g., p12 or p18) and specific antibody. Claims 37-44 are directed toward antibodies specific toward HIV-1 p12, p18, mixtures of antibodies specific for p12 and p25, mixtures of antibodies specific for p18 and p25, and mixtures of antibodies specific for p12, p15, p18, p25, p36, p42, and p80.

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Applicants traverse the rejection and submit that adequate support exists in the specification for the claimed invention. Applicants assert that the specification teaches detailed procedures for

purifying the viral antigens p12, p18, p25, p15, p36, p42, and p80. It was further asserted that the specification teaches using HIV-1 proteins as immunogens for the production of antibodies. Applicants conclude that they were clearly in possession of the claimed antibodies. Concerning the immune complexes, applicants assert that that the specification teaches the preparation of immune complexes formed by patient antisera and viral extracts. It was further asserted that art-recognized methods for preparing immune complexes (i.e., immunoprecipitation) were available at the time of filing. Since patient antisera that reacted with p12, p13, p19, p42, and p80 were identified, applicants conclude that this places the claimed invention within their possession. Applicants' arguments have been duly noted but are not deemed to be persuasive for the reasons of record previously set forth.

As previously noted, the written description requirement under Section 112, first paragraph, stipulates that the claimed subject matter must be supported by an adequate written description that is sufficient to enable anyone skilled in the art to make and use the invention. The courts have decided that the specification must demonstrate that the inventor had possession of the claimed invention as of the filing date relied upon. Although the claimed subject matter need not be described identically, nonetheless, the disclosure relied upon must convey to those skilled in the art that applicants had invented the subject matter claimed. *Ralston Purina Company v. Far-Mar-Co., Inc.*, 227 U.S.P.Q. 177 (C.A.F.C. 1985). *In re Wilder, et al.*, 222 U.S.P.Q. 369 (C.A.F.C. 1984). *In re Wertheim, et al.*, 191 U.S.P.Q. 90 (C.C.P.A. 1976). *In re Blaser, Germscheid, and Worms*, 194 U.S.P.Q. 122 (C.C.P.A. 1977). *In re Driscoll*, 195 U.S.P.Q. 434 (C.C.P.A. 1977). *Utter v. Hiraga*, 6 U.S.P.Q.2d 1709 (C.A.F.C. 1988).

This rejection is based upon the inability of the disclosure to reasonably convey to the skilled artisan that applicants were in

possession of the claimed HIV-1 antibodies and immunological complexes at the time of the filing date relied upon. The specification fails to provide any demonstrative evidence that applicants had generated the claimed antibodies or immune complexes.

5 Moreover, the disclosure only refers to subject matter directed toward a newly isolated virus, the antigens p13, p18, and p25 (refer to disclosure, page 6). The disclosure describes the isolation, purification, and propagation of this virus, designated LAV by applicants. It was further reported that extracts containing p12,

10 p18, and/or p25 were prepared. There was one mention of patient antibodies that displayed reactivity toward the LAV antigens p12, p18, p25, p36, p42, and p80 (refer to page 13 of the disclosure). However, there was no indication that applicants actually contemplated generating, isolating, and characterizing LAV-specific

15 antibodies. Moreover, there is no indication that applicants actually contemplated making and/or using these antibodies or immune complexes comprising these antibodies and the appropriate viral antigen. Accordingly, the skilled artisan would reasonably conclude that applicants were not in possession of the claimed invention at

20 the time of filing. Applicants may obviate the rejection by providing scientific evidence demonstrating that the claimed antibodies and immune complexes were actually generated.

Finality of Office Action

25 4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a). **A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL**

30 **ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS**

MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

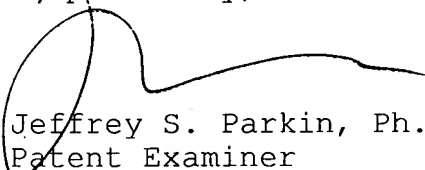
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Correspondence

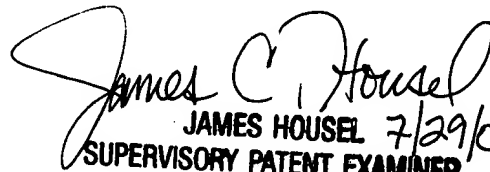
10 5. Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Official communications should be directed toward one of the following Group 1600 fax numbers: (703) 308-4242 or (703) 305-3014. Informal communications may be submitted directly to the Examiner through the following fax number: (703) 308-4426. Applicants are encouraged to notify the Examiner prior to the submission of such documents to facilitate their expeditious processing and entry.

20 6. Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (703) 308-2227. The examiner can normally be reached Monday through Thursday from 8:30 AM to 6:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisors, James Housel or Laurie Scheiner, can be reached at (703) 308-4027 or (703) 308-1122, respectively. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Respectfully,


Jeffrey S. Parkin, Ph.D.
Patent Examiner
Art Unit 1648

27 July, 2002


JAMES HOUSEL 7/29/02
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600